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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/788,746

02/26/2004

Jonathan Weston

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05/23/2006

INTERVET INC.

PATENT DEPARTMENT

PO BOX 318

MILLSBORO, DE 19966-0318

EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/788,746

Applicant(s)

WESTON ET AL.

Examiner

Stacy B. Chen

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 and 17 is/are rejected.
- 7) ☒ Claim(s) 13-15 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/26/04; 5/1/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group I, SEQ ID NO: 6 is acknowledged. The amendment filed March 15, 2006 is acknowledged and entered. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 13-18 are pending.
2. Note that in the restriction requirement of February 15, 2006, the examiner indicated that if Group I was elected, further restriction would be required between the capsid protein, E1, E2, E3, 6K (short) and 6K (long). The examiner did not indicate that the election of a structural protein was an election of species. Since the sequences are not identical and correspond to different proteins, the sequences are not species of each other, and were thus indicated as patentably distinct inventions. Applicant has elected SEQ ID NO: 6, the E2 protein for examination on the merits. All other proteins are withdrawn from consideration, being drawn to non-elected sequences. The restriction requirement is deemed proper and made FINAL.

Specification

3. The specification is objected to because Figure 2 contains sequences that require an identifier(s) in the Brief Description of the Drawings. Correction is required.

Claim Objections

4. Claims 13-18 are objected to for reciting non-elected inventions.

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Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 15 fails to further limit claim 13, because the elected subject matter of both claims is drawn to SEQ ID NO: 6. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to a pharmaceutical composition and a vaccine comprising the recombinant protein of SEQ ID NO: 6, and a pharmaceutically acceptable carrier. Pharmaceutical compositions and vaccines require evidence of a therapeutic benefit, and protection, respectively. The specification as filed does not appear to be enabled for either a composition conferring a therapeutic benefit or protection against pancreatic disease (FPDV) in fish.

The specification teaches that E2 (SEQ ID NO: 6) cDNA was produced from viral RNA by RT-PCR and cloned into the *Not1* site in both pFastBac1 and pcDNA3.1. Insect cells (SF-9) were infected with the recombinant baculovirus construct (pages 16-17). The specification

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discloses that the expressed E2 protein was inactivated and formulated into a water-in-oil based vaccine formulation. Without giving any details about the challenge experiments, Applicant teaches that a “standardized challenge experiment performed at 8 weeks post-vaccination in Atlantic salmon fish showed that protection against challenge with salmon PD virus could be obtained with these recombinant sub-unit vaccines”, page 17, lines 17-19. Applicant states that, “In the experiment, lesions in pancreas, skeletal muscle and heart muscle were scored in ordinal way”, page 17, lines 19-20. Applicant’s experiments and data analysis are implied, but not given. Stating that the standardized challenge experiments were performed, and that the results were scored “in ordinal way”, does not provide evidence of the absence or improvement of lesions in pancreas, skeletal muscle and heart muscle, as a result of the vaccination. Applicant’s conclusion of protection must be backed by evidence. Without this information, one of skill in the art cannot determine whether the claimed composition will confer a therapeutic response or a protective response upon challenge with FPDV. This rejection may be overcome by submitting the data that was used to conclude that the E2 protein confers a therapeutic benefit or protective activity upon challenge.

Conclusion

6. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 5/22/06

Stacy B. Chen
Primary Examiner
May 22, 2006